

**REMARKS**

Claims 1-29 are pending in the present application. In the Office Action, all claims were rejected. In response to the Office Action, no claims have been amended. Reexamination and reconsideration of the claims in view of the arguments discussed below is respectfully requested.

Claim Rejections – 35 U.S.C. § 102

In the Office Action, claims 1, 2, 7-11, 14, and 17 were rejected under 35 U.S.C. § 102(e) as being anticipated by US Patent Publication No. 2004/0010303 to Bolea et al. (hereinafter referred to as Bolea). Such rejections are traversed for at least the following reasons.

Claim 1 presently recites:

1. **A method of treating a stiffened blood vessel**, said method comprising at least substantially **encasing a stiffened portion of said blood vessel** with an elastic membrane formed of biocompatible material, such that said membrane engages said stiffened portion of said blood vessel to thereby **reduce the external diameter** of said stiffened-portion of said blood vessel, **passively carry at least a portion of blood pressure loads** acting on said blood vessel throughout systole and diastole and **reduce the effective stiffness** of said stiffened portion of said blood vessel, said elastic membrane having **a stiffness less than** the stiffness of said stiffened portion of said blood vessel.

Bolea fails to teach or suggest each and every element of claim 1. Bolea relates to devices and methods for controlling the bioreflex system of a patient to treat and/or manage cardiovascular and renal disorders and their underlying causes and conditions (see paragraph [0002]). Bolea describes the positioning of a bioreceptor activation device 70, comprising an electrode structure, on or over a vascular structure (particularly a blood vessel, such as the carotid artery) immediately adjacent native bioreceptors 30 located within the vascular structure (see paragraphs [0067] – [0068]). The bioreceptors are sensitive to blood pressure within the blood vessel, sending signals to the brain which in turn regulate the cardiovascular system to maintain normal blood pressure, in part through activation of the sympathetic nervous system (see paragraph [0009]). The electrode structure stimulates the bioreceptors, mimicking a

pressure rise, sending a signal to the brain which then regulates the cardiovascular system, predominantly relaxing smooth muscle in the blood vessel wall, to reduce the perceived increase in blood pressure. Such a bioreceptor activation device would only be effective in application to a normal, or near normal, blood vessel whose bioreceptor nerve endings and muscle tissue are functioning normally. The bioreceptor activation device 70 is positioned to have electrical contact with the blood vessel wall throughout systole and diastole, without mechanically distorting the wall or impinging on the lumen of the blood vessel.

Applicant submits that Bolea is not relevant to the presently claimed invention and therefore Bolea fails to anticipate claim 1 and the claims depending therefrom.

Firstly, Bolea fails to teach or suggest a method of treating a stiffened blood vessel as recited in the preamble of claim 1. The Examiner has relied on reference to paragraph [0012] in asserting that Bolea does in fact teach or disclose such a method. However, paragraph [0012] merely generically refers to “hypertension, heart failure and their associated cardiovascular and nervous system disorders”. While stiffening of arteries (particularly the aorta) may be associated with some forms of hypertension, stiffening is not necessarily associated with all forms of hypertension and in fact the type of hypertension described in Bolea (at paragraph [0004]) is described as occurring when arterioles constrict. Further, as noted above, the method described in Bolea is applicable to normal, or at least near normal, arteries whose bioreceptor nerve endings and muscle tissue are functioning normally, as opposed to a stiffened blood vessel.

Secondly, Bolea fails to teach or suggest encasing a stiffened portion of a blood vessel for similar reasons to those noted above. The Examiner has relied on reference to Figure 12 in asserting that Bolea does disclose such encasement. Figure 12, however, does not suggest that the portion of blood vessel that is encased is in any way stiffened, as recited by claim 1.

Thirdly, Bolea does not teach or suggest reducing the external diameter of a portion of a blood vessel by engagement of a membrane, as also recited by claim 1. It appears that the Examiner is relying on paragraph [0113] in support of the assertion that the diameter is reduced. There is, however, no reference in paragraph [0113] to a reduction in diameter of the treated vessel. In fact from a review of the figures of Bolea, particularly Figures 4A, 4B and 12,

it is immediately apparent that the bioreceptor activation device does not reduce the diameter of the vessel being treated.

Fourthly, Bolea fails to teach or suggest a membrane that passively carries at least a portion of blood pressure loads acting on the blood vessel throughout systole and diastole, as recited by claim 1. It appears that the Examiner has again relied on paragraph [0113] in support of the assertion that there is such disclosure. Paragraph [0113] does not, however, make any reference to the carrying of blood pressure loads. In any event, paragraph [0113] relates to the rib structure 316 of the activation device 300 depicted in Figure 13. No aspect of the ribs 316, or the activation device 300 itself, could be considered to be in the form of an elastic membrane and, accordingly, the disclosure of this paragraph fails to teach or suggest the claimed feature. The ribs 316 are also described in paragraph [0113] as being formed of a relatively stiff material.

Fifthly, Bolea does not teach or suggest use of a membrane to reduce the effective stiffness of a stiffened portion of a blood vessel, as recited by claim 1. The Examiner has yet again relied on the disclosure of paragraph [0113] in support of this assertion, but there is no relevant disclosure relating to this feature to be found either in paragraph [0113] or anywhere within Bolea. Given that the bioreceptor device of Bolea is designed merely to make electrical contact with the artery wall, and not to take any mechanical loads, it will not have any notable effect on the stiffness of the vessel on which it is positioned.

Sixthly, Bolea fails to teach or suggest an elastic membrane having a stiffness less than the stiffness of a stiffened blood vessel to which it is applied, as recited by claim 1. The Examiner has again relied on the disclosure of paragraph [0113]. As noted above, however, this paragraph discusses the rib structure 316 of the activation device 300 depicted in Figure 13, which is not in the form of an elastic membrane, and as noted above, is described as being relatively stiff.

Claim 7 was also rejected as being anticipated by Bolea. Such rejections are traversed for at least the following reasons. Bolea fails to teach or suggest that the stiffened portion of the blood vessel being treated is in a stiffened and dilated state prior to treatment, as claim 7 recites. The Examiner has relied on paragraph [0012] in asserting that this feature is disclosed. Paragraph [0012], however, makes no reference to the state of the blood vessel being treated. From the various figures of Bolea, it seems clear that the blood vessel being treated is

not in a dilated state, and, based on the fact that the bioreceptor activation device of Bolea will only work with a normal or near normal artery, a skilled person would expect that the vessel would not be in a stiffened or dilated state.

Claim 14 was rejected as being anticipated by Bolea. Such rejections are traversed for at least the following reasons. Bolea fails to teach or suggest securing end portions of a membrane by way of interlocking structures formed on, or fixed to, each of the opposing end portions, as recited by claim 14. The Examiner has asserted that suture flaps 308 constitute such interlocking structure. However, the suture flaps 308, best depicted in Figure 12, constitute the ends of the membrane and are not interlocking. The suture flaps are secured, without interlocking, by sutures 309.

Claim 17 was rejected as being anticipated by Bolea. Such rejections are traversed for at least the following reasons. Bolea fails to teach or suggest a membrane in the form of a spiral, as recited by claim 17. The Examiner has considered the ribs 316 of Figure 13 to form such a membrane in the form of a spiral. Firstly, however, the ribs of Figure 13 do not constitute a membrane as discussed above. Further, the ribs 316 are formed of a series of longitudinally spaced and parallel arcs rather than a spiral.

Because the cited reference fails to teach or suggest each and every element of the claimed invention, anticipation cannot be established under 35 U.S.C. § 102(e). Applicant respectfully requests withdrawal of the § 102(e) rejection and allowance of claim 1 and the claims depending therefrom.

#### Claim Rejections 35 U.S.C. § 103

##### Bolea in view of Khanghani

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 6,984,201 to Khanghani et al. (hereinafter Khanghani). Such rejections are traversed for at least the following reasons.

Claims 3-4 depend indirectly from independent claim 1 which has been distinguished from Bolea as discussed above. Khanghani fails to provide the elements missing from Bolea.

Khanghani discloses an active blood circulation assistance device for location around a blood conduit. The device has an inflatable bladder that is moveable between a contracted form and an expanded form for compressing the blood conduit to provide counterpulsation (Abstract). When the bladder moves from the contracted form to the expanded form at diastole, the blood conduit is compressed and blood in the conduit is displaced, thereby reducing cardiac loading (col. 9, lines 20-29). Khanghani fails to teach or suggest a method of treating a stiffened blood vessel. Moreover, the cited reference also fails to teach or suggest encasing a stiffened portion of the blood vessel. Additionally, Khanghani's device actively inflates and deflates, therefore Khanghani also fails to teach or suggest passively carrying at least a portion of the blood pressure loads, as recited by claim 1. Furthermore, because Khanghani's inflatable bladder displaces blood in the vessel during diastole, the bladder must be stiffer than the blood vessel to overcome the diastolic pressure therein, and hence Khanghani also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel, as recited by amended claim 1.

Additionally, one of skill in the art would not combine Khanghani with Bolea. Bolea's device relies on electrical stimulation of a baroreceptors to obtain a therapeutic result, whereas Khanghani's device utilizes a pumping device. Combining the two references would require redesign and reconstruction of Bolea's device and would change the basic principle under which Bolea's device operates, therefore the teachings of Bolea and Khanghani are not sufficient to establish *prima facie* obviousness. M.P.E.P. § 2143.01. The combination of Bolea and Khanghani is therefore improper and constitutes impermissible hindsight reconstruction. The claimed invention as a whole, not just its individual elements must be considered and it is inappropriate to use hindsight when guided by the applicant(s)'s disclosure

Therefore, because the cited references, alone or in combination fail to teach or suggest each and every element of the claimed invention, and because one of skill in the art would not combine the cited references, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 3-4.

Bolea in view of Hegde

Claims 5 and 28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent Publication No. 2004/0147803 to Hegde et al. (hereinafter Hegde). Such rejections are traversed for at least the following reasons.

Claim 5 depends from independent claim 1 which has been distinguished from Bolea as discussed above. Hegde fails to provide the elements missing from Bolea.

As noted by the Examiner, Bolea does not teach applying the device to a grafted, synthetic portion of a blood vessel. Bolea further fails to teach or suggest reduction of the external diameter of the portion of the blood vessel being treated, passively carrying at least a portion of blood pressure loads acting on a blood vessel throughout systole and diastole, reducing the effective stiffness of a treated portion of the blood vessel and an elastic membrane having a stiffness less than the stiffness of the treated portion of the blood vessel, as discussed above in relation to claim 1. Hegde does not teach or suggest these additional features

Hegde discloses a vascular assist device that compresses a blood vessel in response to the cardiac cycle, resulting in displacement of blood through the vessel. However, Hegde fails to include many of elements recited in claim 1, including a method of treating a stiffened blood vessel, encasing a stiffened portion of the blood vessel, reducing the external diameter of the stiffened blood vessel, passively carrying at least a portion of the blood pressure loads, reducing the effective stiffness of the stiffened portion of the blood vessel, and an elastic member having a stiffness less than the stiffness of the stiffened portion of the blood vessel. Therefore, for at last the same reasons discussed above with respect to claim 1, Hegde fails to provide the elements missing from Bolea.

Further, Applicant contends that it would not have been obvious to one of ordinary skill in the art to have used the device of Bolea on a grafted, synthetic vessel given that grafted, synthetic vessels do not have bioreceptors, and, accordingly, the bioreceptor activation device of Bolea would not have any effect on such a grafted, synthetic vessel.

Bolea in view of Chuter

Claims 6 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 5,387,235 to Chuter (hereinafter Chuter). Such rejections are traversed for at least the following reasons.

Claim 6 depends from independent claim 1 which has been distinguished from Bolea as discussed above. Chuter fails to provide the elements missing from Bolea.

Chuter discloses a prosthesis for treating an aneurysm (Abstract), not a method for treating a stiffened blood vessel. Chuter's prosthesis is disposed internally in a vessel (Fig. 15) therefore Chuter's device does not encase a stiffened portion of the blood vessel, nor does his device reduce external diameter of the stiffened portion of the blood vessel and reduce the effective stiffness of the stiffened portion of the blood vessel, as recited in independent claims 1 and 28.

Moreover, one of skill in the art would not combine Bolea and Chuter. Bolea's device is used to electrically stimulate baroreceptors with an external device, while Chuter's device is implanted internally in a vessel. Implanting a device clearly involves a different principle of operation than Bolea's external device, therefore the combination is insufficient to support a *prima facie* case of obviousness under 35 U.S.C. § 103(a).

Claim 29 depends from independent claim 28 which has been distinguished from Bolea for at least the same reasons as discussed above with respect to claim 1. And similarly, Chuter fails to provide the elements missing from claim 29, also, one of skill in the art would not combine Chuter and Bolea as discussed above.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, and because one of skill in the art would not combine the two references, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 6 and 29.

Bolea in view of Barefoot

Claim 12 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 3,726,279 to Barefoot et al. (hereinafter Barefoot). Such rejections are traversed for at least the following reasons.

Claim 12 depends indirectly from independent claim 1 which has been distinguished from Bolea as discussed above. Barefoot fails to provide the elements missing from Bolea.

Firstly, Barefoot fails to teach or suggest a method of treating a stiffened blood vessel. Barefoot discloses a hemostatic vascular cuff that is used to control hemorrhaging of suture lines in vessels following vascular surgery (Abstract; col. 4, lines 19-21). The only other application of Barefoot's vascular cuff is described in column 4, lines 12-13, as reinforcing the walls of diseased or damaged vessels. Barefoot does not disclose, teach or suggest using his cuff to treat a stiffened blood vessel by encasing a stiffened portion of the blood vessel, as is also recited by claim 1. Barefoot further fails to teach or suggest a reduction of the effective stiffness of a stiffened portion of a blood vessel, and the use of an elastic membrane having a stiffness less than the stiffness of the stiffened portion of the blood vessel. Barefoot seeks to control hemorrhaging of a sutured vessel by reinforcing the sutured portion of the vessel. The reinforcement reduces expansion of the sutured portion so that the suture lines will not open up and allow bleeding (see Abstract: column 4, lines 1-11 and column 4, lines 19-21). Accordingly, Barefoot's vascular cuff would seem to have the result of increasing the effective stiffness of the vessel, contrary to what is required of claim 1. It would also follow that the stiffness of the material from which the cuff is formed, which is described as including a semi-rigid core formed from a resilient material such as nylon or polypropylene (see column 1, lines 32-35 and column 3, lines 4-6) would have a stiffness greater than that of the encased portion of the sutured vessel.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants therefore respectfully request withdrawal of the § 103(a) rejection, and allowance of claim and 12.

Bolea in view of Spaulding

Claim 13 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 5,304,200 to Spaulding (hereinafter Spaulding). Such rejections are traversed for at least the following reasons.

Claim 13 depends from independent claim 1, which has been distinguished from Bolea as discussed above. Spaulding fails to provide the elements missing from Bolea.

Spaulding discloses a stent, and fails to teach or suggest encasing a stiffened portion of a blood vessel with an elastic membrane as recited in claim 1. Moreover, Spaulding's stent is positioned inside a blood vessel and therefore it does not reduce the external diameter of the stiffened blood vessel, nor does it passively carry at least a portion of blood pressure loads. Because the purpose of a stent is to provide scaffolding to a vessel, it cannot reduce effective stiffness of the stiffened portion of the blood vessel, as also recited by the claim.

Because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claim 13.

Bolea in view of Jones

Claim 15 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 4,202,349 to Jones (hereinafter Jones). Such rejections are traversed for at least the following reasons.

Claim 15 depends indirectly from independent claim 1 which has been distinguished from Bolea as discussed above. Jones fails to provide the elements missing from Bolea.

Jones discloses markers that are attached to a blood vessel in order to allow verification of pulsatile blood flow under fluoroscopy by observing movement of the markers (Abstract). Therefore, Jones fails to teach or suggest a method of treating a stiffened blood vessel or encasing a stiffened portion of the blood vessel with an elastic membrane. Moreover, Jones also fails to teach or suggest reducing external diameter of the stiffened-portion of the

blood vessel, reducing effective stiffness of the blood vessel or carrying at least a portion of the blood pressure loads, all recited in the claim.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 15.

Bolea in view of Dusbabek

Claim 16 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent Publication No. 2001/0007082 to Dusbabek et al. (hereinafter Dusbabek). Such rejections are traversed for at least the following reasons.

Claim 16 depends indirectly from independent claim 1 which has been distinguished from Bolea as discussed above. Dusbabek fails to provide the elements missing from Bolea.

Dusbabek's system is placed inside a blood vessel and thus Dusbabek's system does not encase a stiffened portion of the blood vessel, nor does it reduce the external diameter of the stiffened blood vessel and reduce the effective stiffness of the stiffened portion of the blood vessel, as recited in claim 1.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 16.

Bolea

Claims 18-24 were rejected under 35 U.S.C. § 103(a) as being unpatentable in view of Bolea. Applicant notes that the Office Action on page 6 states that claims 18-24 were rejected "as being anticipated by Bolea et al." Applicants assume that this is a typographical error and that the rejection is based on obviousness since the Office Action lists the rejection under 35 U.S.C. § 103(a), not § 102. Moreover, the Office Action on page 6 further

acknowledges that Bolea is silent as to the properties of size and stiffness, therefore claims 18-24 cannot be anticipated by Bolea. Applicant will address the rejection under the assumption that it was based on obviousness, not anticipation. If this assumption is incorrect, Applicant respectfully requests the opportunity to respond.

Such rejections are traversed for at least the following reasons. Claims 18-24 depend either directly or indirectly from independent claim 1 which has been distinguished from Bolea as discussed above. Therefore, for at least the same reasons discussed above, claims 18-24 are also distinguished from Bolea.

Moreover, given that Bolea is concerned with merely positioning electrode structures in electrical contact with a blood vessel wall and is not at all concerned with carrying blood pressure loads or affecting the effective stiffness of the vessel, Bolea provides no incentive for tailoring specific mechanical properties of a membrane to provide the stiffness and cardiac load altering effects of the method of the present invention.

Applicants respectfully request withdrawal of the § 103(a) rejection and allowance of claims 18-24.

Bolea in view of Silvestrini

Claims 25-26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent No. 4,834,755 to Silvestrini et al. (hereinafter Silvestrini). Such rejections are traversed for at least the following reasons.

Claims 25-26 depend directly from independent claim 1 which has been distinguished from Bolea as discussed above. Silvestrini fails to provide the elements missing from Bolea.

Silvestrini's device, when used as a vascular prosthesis, is used to replace a section of a blood vessel. Therefore, Silvestrini fails to teach or suggest encasing a stiffened portion of the blood vessel and reducing the external diameter of the stiffened portion of the blood vessel. Moreover, Silvestrini also fails to teach or suggest reducing the effective stiffness of the stiffened portion of the blood vessel.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be

established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claims 25-26.

Bolea in view of Wellman

Claim 27 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Bolea in view of U.S. Patent Publication No. 2003/0065303 to Wellman et al. (hereinafter Wellman). Such rejections are traversed for at least the following reasons.

Claim 27 depends directly from independent claim 1 which has been distinguished from Bolea as discussed above. Wellman fails to provide the elements missing from Bolea.

Wellman discloses a method of treating diseased blood vessels, and particularly diseased blood vessels that have a narrowed blood vessel lumen, and thus reduced effective diameter. Such vessels are treated by increasing the effective diameter of the diseased blood vessel and maintaining the increased diameter for a sufficient period of time (see, for example, paragraphs 0003, 0005, 0006 of Wellman). The exemplary embodiments are described in terms of the diseased blood vessel having an atherosclerotic plaque along its wall (see, for example, paragraphs 0008, 0009 and 0033 and atherosclerotic plaque 120 depicted in Figure 1). The existence of atherosclerotic plaque on a blood vessel wall does not, however, result in a stiffened blood vessel as discussed in the last response. Accordingly, a blood vessel exhibiting atherosclerotic plaque along its wall cannot be considered a stiffened blood vessel.

Wellman further fails to teach or suggest reducing the external diameter of a blood vessel. The methods of Wellman all involve disrupting the integrity of at least one layer of the diseased blood vessel, promoting the growth of an aneurysm either by way of chemical treatment (for example, application of a proteolytic enzyme directly to the blood vessel) or by mechanical treatment (such as by puncturing the blood vessel wall). The methods of treatment of Wellman are all thus directed at increasing the diameter of the diseased blood vessel, through growth of an aneurysm, rather than reducing the diameter of a stiffened portion of a blood vessel, as is the case with the present invention.

Wellman also fails to teach or suggest the use of an elastic membrane formed of biocompatible material. The body 52 of the sponge 50 depicted in Figure 5 of Wellman, is not

an elastic membrane but merely a topical drug applicator that is loaded with an active therapeutic agent and placed on the affected vessel, providing for delayed drug delivery to a diseased region of a blood vessel. While the body 52 of the sponge 50 is described at paragraph 0041 of Wellman as providing mechanical support to the diseased region of the blood vessel, this support would only be temporary and relatively inconsequential. The sponge 50 is described (at paragraph 0042) as being formed of a bioabsorbable polymer such that it will be absorbed (and thereby effectively disappear) once it has carried out its primary purpose of delivering a therapeutic agent to the blood vessel over a relatively short period of time. The sponge 50 must also allow for an increase in the diameter of the blood vessel as the aneurysm grows.

Wellman further fails to teach or suggest reduction of the effective stiffness of a stiffened portion of a blood vessel, or use of an elastic membrane having a stiffness less than the stiffness of the stiffened portion of the blood vessel. As noted above, Wellman is not directed whatsoever to a method of treating a stiffened blood vessel by reducing the diameter of the blood vessel, reducing the effective stiffness of the blood vessel as noted above. Wellman, and particularly the embodiment depicted in Figure 5, is directed at utilizing a sponge merely to deliver a therapeutic agent to a diseased portion of a blood vessel over a limited period, and then bioabsorb to allow for the growth of an aneurysm to thereby increase the diameter of the blood vessel. The disclosure of Wellman provides no incentive for a person of ordinary skill in the art to consider use of an elastic membrane and the stiffness properties to reduce the external diameter of a stiffened portion of a blood vessel and reduce the effective stiffness of that stiffened portion of a blood vessel. Wellman in fact teaches directly away from the present invention, promoting a substantial increase in the diameter of a diseased blood vessel through growth of an aneurysm.

Wellman also fails to teach or suggest the use of an elastic membrane to passively carry at least a portion of blood pressure loads acting on the blood vessel throughout systole and diastole. The sponge 50 of Wellman merely acts to carry and deliver a drug to a diseased portion of a blood vessel and generally support the blood vessel. There is no suggestion that the sponge carries blood pressure loads acting throughout systole and diastole, and there would certainly be no incentive for a person of ordinary skill in the art to configure a sponge in such a manner,

given its purpose. Further, with the sponge of Wellman being described as being bioabsorbable, it would clearly be unable to carry any loads once it has been absorbed.

Therefore, because the cited references, alone or in combination, fail to teach or suggest each and every element of the claimed invention, *prima facie* obviousness cannot be established under 35 U.S.C. § 103(a). Applicants respectfully requests withdrawal of the § 103(a) rejection and allowance of claim 27.

### CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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